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How are normal sleeping controls selected? A systematic review of cross-sectional insomnia studies, and a standardised method to select healthy controls for sleep research

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Highlights

- Criteria for assessing Good Sleeper Controls are rarely applied in full.
- Screening is applied most rigorously at the level of clinical disorders.
- We provide a definition of normal sleep and assessment methods.

Abstract

There appears to be some inconsistency in how normal sleepers (controls) are selected and screened for participation in research studies for comparison with insomnia patients. The purpose of the current study is to assess and compare methods of identifying normal sleepers in insomnia studies, with reference to published standards. We systematically reviewed the literature on insomnia patients which included control subjects. The resulting 37 articles were systematically reviewed with reference to the five criteria for normal sleep specified by Edinger et al. (2004). In summary, these criteria are: evidence of sleep disruption; sleep scheduling; general health; substance/medication use; and other sleep disorders. We found sleep diaries, PSG, and clinical screening examinations to be widely used with both control subjects and insomnia participants. However, there are differences between research groups in the precise definitions applied to the components of normal sleep. We found that none of reviewed studies applied all of the Edinger et al. criteria, and 16% met four criteria. In general, screening is applied most rigorously at the level of a clinical disorder, whether physical, psychiatric, or sleep. While the Edinger et al. criteria seem to be applied in some form by most researchers, there is scope to improve standards and definitions in this area. Ideally, different methods such as sleep diaries and questionnaires would be used concurrently with objective measures to ensure normal sleepers are identified, and descriptive information for control subjects would be reported. Here, we have devised working criteria and methods to be used for assessment of normal sleepers. This would help clarify the nature of the control group, in contrast to insomnia subjects and other patient groups.

Keywords: normal sleepers, good sleep, insomnia, assessment, screening, methods

Introduction

Given the significance of sleep to well-being[1], consistency in how research participants are selected is important. Indeed, this is accepted among clinicians, with diagnostic systems used to identify different sleep disorders[2-4]. While it is acknowledged that adherence to consensus categorization systems is important with clinical groups, such high standards have not always been applied to the selection of normal sleepers (controls). As a result, the precise definitions, and consequently methods, applied to identify normal sleepers are variable within sleep research. The purpose of the current study was to investigate exactly how control subjects are assessed, in comparison to insomnia patients. The selection of control subjects is important, as group differences may be caused by these subjects rather than the patient group, if normal sleepers are not well defined and selected. Furthermore, consistency in how normal sleepers are defined is important in order to compare results between studies. These results have broader implications for the selection of normal sleepers or control subjects within sleep research overall.

A definition of normal sleepers (controls) has been provided, and five criteria have been identified. The research diagnostic criteria (RDC) for normal sleepers specifies that normal sleepers should show no evidence of sleep disruption (Criterion A), and that the timing of sleep should be both regular and conventional (Criterion B)[2]. As such, both the quality of sleep and its timing are thought to be important in defining normal sleepers. However, these components of normal sleep are not always applied in practice. For example, the Pittsburgh Sleep Quality Index, or PSQI[5], and the Insomnia Severity Index, or ISI[6], have been used to categorize participants as poor and normal sleepers[7-11]. In this approach, those participants scoring below threshold are categorized as normal sleepers. Others seem to define acceptable levels of sleep disruption, or to select healthy subjects based on the absence of insomnia disorder rather than the presence of normal or good sleep. However, such

differences in methods may lead to different groups being used as a comparison, with some subjects better sleepers than others. Furthermore, evidence of sleep disruption is only one component of research diagnostic criterion for control subjects[2].

The second component of research diagnostic criterion for control subjects includes two elements; firstly, that sleep timing is conventional[2]. Some authors specify habitual bed times and rise times as inclusion criteria. This is also pertinent to circadian rhythm sleep disorders, and an individual's preference for morningness or eveningness is relevant to their sleep scheduling. The morningness-eveningness questionnaire (MEQ) was developed to assess diurnal preference[12], and has been used to identify morning and evening types[13-17]. Furthermore, the RDC also specifies that timing of sleep is stable. Sleep diaries can be used to monitor adherence to a sleep schedule[15, 18, 19], and assess reported sleep patterns and habits, as well as their variability[20-22]. They provide information about the daily timing of sleep, as well as measures of sleep continuity (e.g. wake after sleep onset), and its qualitative experience, and sleep diaries are regarded as the "gold-standard" in measuring subjective sleep experience[23]. However, while a routine sleep schedule is thought to be important to normal sleep[24, 25], there seems to be a lack of clarity as to how much variability in sleep scheduling is acceptable in practice.

To fully understand the development and maintenance of sleep disorders, such as insomnia, it is necessary to understand the processes in normal sleep[24-26]. However, this is hampered when the methods of assessment of normal sleepers differ, and this seems especially pertinent when research subjects are recruited from a student population, whose sleep can be irregular, and of poor quality[27].A majority of potential participants (i.e. normal sleepers) might be expected to show a moderate level of vulnerability towards poor sleep or insomnia, in keeping with a normal distribution, e.g. Yiend[28].When insomnia subjects and normal

sleepers are compared on the effects of poor sleep, the daytime effects of poor sleep are similar, although more severe for insomnia patients[29], and both groups use comparable criteria to judge sleep quality[30]. However, in insomnia patients the daytime effects associated with sleep seem especially important, both in theory[25, 31] and to patients themselves[29, 32].Current research is aimed at investigating the etiology of insomnia disorder, e.g. the development of chronic insomnia from acute insomnia[33], and this suggests the importance of additional factors in the development of insomnia disorder. For example, insomnia patients might experience the effects of sleep disruption more severely, or report more frequent nights of poor sleep[28], and changes in sleep architecture could contribute towards this transition[33]. Furthermore, in keeping with a normal distribution[28], some normal sleepers could show evidence of sleep disruption, while not quite endorsing insomnia, e.g.[25]. Normal sleepers also could be different from good sleepers, who would be expected to report good sleep without sleep disruption. Although investigating the differences between good sleep and normal sleep is beyond the scope of the current paper, understanding definitions applied to control subjects seems an important first step. As such, we have conducted a systematic review on how control subjects are assessed for study inclusion within insomnia research. We then outline recommendations for assessing normal sleep, and suggest methods of assessment.

Methods

A literature search was conducted within six key sleep-society affiliated journals. In particular, Sleep is the official publication of the Associated Professional Sleep Societies, the Journal of Sleep Research is published on behalf of the European Sleep Research Society, and Sleep Medicine is the official journal of the World Association of Sleep Medicine and International Pediatric Sleep Association. Behavioral Sleep Medicine is official journal of the Society of Behavioral Sleep Medicine, Chronobiology International is the official journal for

the International Society for Chronobiology, the American Association for Medical Chronobiology and Chronotherapeutics, and the Society for Light Treatment and Biological Rhythms. The Journal of Biological Rhythms is the official publication of the Society for Research on Biological Rhythms. The Journal of Clinical Sleep Medicine, an official publication of the American Academy of Sleep Medicine, was not included due to a lack of institutional access. The literature search was confined to these journals, as they were expected to apply more stringent criteria towards how sleep groups are defined. The anticipated effect of this was to bias the literature search towards more conservative or stringent methodologies with regards to sleep.

The "Web of Knowledge" (http://wok.mimas.ac.uk/) search engine was used to access database entries for these journals. Key search terms were "poor sleep" or "insomnia", and a large number of results was found initially (24, 782 search results). These results were filtered by selecting article types which were published in English, and we selected those studies based on adults (see Figure 1). We further refined these results to identify those papers where an insomnia sample was compared against controls, and 64 abstracts were then manually reviewed (Figure 1.). These papers were all published from 2005 – present, following the publication of the RDC in 2004. As the focus of this review was on methods of assessment, sample size was not considered as an exclusion criterion.

Those papers without a suitable control group were excluded (for example, intervention studies), giving a final sample of 37 (Table 1.). All papers included an insomnia patient group, and the majority (30) used patients with primary insomnia. Data were extracted by selecting those methods relevant to each of the 5 criteria in the RDC[2]. In general, specific details as to insomnia, and methods of sleep assessment, were coded within Criterion A. Information relevant to circadian rhythm sleep disorders and test time, as well as work and travel was contained within Criterion B. In keeping with the RDC, methods relevant to physical and psychiatric health, medication use and substance abuse, and sleep disorders in general, were coded separately under Criteria C, D and E. All data were coded as described in the original papers; and not subject to interpretation at initial encoding.

Results

Criterion A

We recorded how control groups were defined with regards to Criterion A, i.e. “the individual has no complaints of sleep disturbance or daytime symptoms attributable to unsatisfactory sleep”. Firstly, the definitions applied to control subjects are summarized. These definitions varied, from “healthy”, “normal/good sleepers”, and “typically good sleepers”, and included descriptions such as no subjective complaints of sleep difficulties or insomnia, or sleep or insomnia complaints. More detailed definitions included that subjects characterize their sleep as restorative or refreshing, sleep satisfaction, relatively imperturbable sleep, and falling asleep as soon as your head touches the pillow. Additional specifications included that subjects report no history of sleep disorders or insomnia, either current or in the past, and

objective sleep thresholds were also used. Sleep questionnaires can be used to quantify sleep-related thresholds, and 5% of studies reported cut-off scores or descriptive information for the Pittsburgh Sleep Quality Index (PSQI), with the Insomnia Severity Index (ISI) similarly used by 30% of papers. Many studies (51%) reported sleep diary parameters of control subjects, and a majority of studies (65%) reported descriptive sleep information from PSG measures, with 2 studies (5%) reporting actigraphy-derived sleep parameters.

In terms of meeting criteria A, we required papers to have explicit exclusion criteria based on both measures of sleep disruption (i.e. sleep continuity), and daytime effects (e.g. report sleep as restorative). In total 8% of papers met this criterion.

Criterion B

Criterion B is defined as an individual having "a routine standard sleep/wake schedule characterized by regular bedtimes and rising times". To assess this, we recorded information relevant to sleep timing within the articles. Four studies (11%) reported average bed times/rise times, and the range of subjects' sleep timing was reported by 30% of studies, either descriptively, or as inclusion criterion (e.g. to confirm consistency of habitual sleep patterns with a specified sleep laboratory schedule). One study reported an actigraphy-derived measure of circadian phase, and another reported a measure of diurnal preference. Other relevant exclusion criteria included shift working patterns and long range travel, as well as circadian rhythm sleep disorders or abnormal usual sleep schedules. With regards to meeting criteria for sleep timing, adherence to this criterion was defined by explicit exclusion criteria for sleep timing, i.e. bed times and rise times, and met by 30% of papers.

Criterion C

Criterion C is defined as “no evidence of a sleep-disruptive medical or mental disorder”.

A majority of studies applied general medical examinations, which were used to assess health, and the absence of signs or symptoms of a disorder (e.g. blood screening tests). Twelve studies (32%) also reported BMI scores, and 56% used or reported data from additional questionnaire screening measures for symptoms of mental health conditions, such as depression or anxiety. At least one medical condition was excluded for by 84% of studies, and specific disorders listed included unstable hypertension, thyroid disorders, seizure disorders, neurodegenerative disease, chronic pain, significant head trauma or loss of consciousness, cardiovascular or respiratory disease, diabetes, dementia, multiple sclerosis, pregnancy, hepatitis, cancer, Parkinson's disease, rheumatoid arthritis, and gastroesophagael reflux disease, asthma, chronic obstructive pulmonary disease. At least one psychiatric disorder was excluded for by 86% of studies, which included mood disorders, psychotic disorders, anxiety disorders, eating disorders, somatoform disorders, and substance abuse disorder (this latter is considered in more detail under Criterion D). When this criterion was judged via exclusions for medical and psychiatric disorders, 70% of papers met this criterion.

Criterion D

Criterion D is defined as "no evidence of sleep disruption due to a substance exposure, use, abuse, or withdrawal". Generally, articles assessed subjects for evidence of a disorder which would be relevant to this criterion. In total, 76% of articles reported exclusion criteria as to medication use, and most commonly selected those subjects who were either not on medication, not using medication affecting sleep, or taking CNS-active agent, psychotropic agents, or hypnotics. Drug abuse or dependence was excluded by 57% of studies, with alcohol, caffeine, or nicotine consumption mentioned by 59% of articles. When D was defined as explicit exclusions for substance abuse and medication use, 43% of studies met criterion.

Criterion E

The final criterion is “no evidence of a primary sleep disorder”. A number of studies (59%) reported PSG screening for sleep apnea and limb movements in control subjects. Evidence of sleep disruption, or other sleep disorders, was assessed by 76% of articles and included evidence of current disorder, evidence of symptoms, and/or past (or family) history. In addition, other disorders (e.g. nocturia, enuresis, bruxism) were mentioned occasionally. When this criterion was defined as explicit exclusion criteria for sleep disorders in conjunction with PSG, 54% of papers met criteria.

In total, no papers were judged to meet all five criteria. 16% met four criteria, 22% of papers met three criteria, 30% met two criteria, and 14% met one criterion, with 19% of papers meeting none. The complete table as to how papers were coded is available online in Supplemental Material I.

Discussion

Overall, the selected articles screened subjects well for potential disorders (whether physical, psychiatric, or sleep). However, the criteria applied to control subjects differed between studies, and information relevant to criteria seemed to be used to describe subjects groups, rather than as explicit a priori exclusion criteria as such. There are also differences between laboratories as to how exactly subjects are identified, and Criteria A and B seem to require clarity. While Edinger et al.[2] define A as “no complaints of sleep disturbance, or daytime symptoms attributable to poor sleep”, there is a lack of consensus as to how exactly this should be defined. For example, some specify sleep diary criteria, while others use questionnaire cut-offs, and/or a lack of ‘sleep complaint’, or absence of insomnia disorder as

such. We would interpret A as comprising three main elements, firstly, whether an individual is experiencing sleep disturbance (i.e. via sleep duration or sleep continuity measures). Secondly, whether subjects are satisfied with their sleep, and experience good sleep quality. In addition to this, the experience of adverse sleep-related daytime effects would lead to the exclusion of control subjects.

Criterion B, defined as "a routine standard sleep/wake schedule characterized by regular bedtimes and rising times"[2] seems to comprise several components, in particular, the habitual timing of sleep, and its stability. Evidence of circadian rhythm sleep disorders often seemed to be used to assess this criterion, overlapping with Criterion E. While a majority of authors reported use of sleep diaries, which can be used to assess this, it is often unclear exactly how these components are defined in practice. Many authors defined normal sleep timing parameters, although normality would seem to depend on the study sample, and would be affected, for example, by age[34]. Sleep timing, chronotype, and sleep quality seem to be interlinked[35-37]. Furthermore, while the stability of sleep timing seems to be important for control subjects, this component seems to be rarely directly addressed, other than by shift work, and it is unclear whether any exclusions were made based on sleep timing stability as such. The variability, or stability, of sleep timing could also contribute to good sleep (e.g.[25]), and differences in sleep timing between the working week and at the weekend could contribute to variability in sleep timing[38], and social jetlag[39, 40]. Questionnaire measures such as the Sleep Timing Questionnaire[38] could be used to quantify the components of sleep timing, as could measures derived from sleep diary parameters. We would define B as conventional (for a particular population) bed times and rise times, which are consistent (± one hour, at least four days a week).

For the remaining criteria, there seems to be some ambiguity as to the precise definitions. Furthermore, clear definitions are needed in order to standardize methods and measures. For example, we would interpret C as a currently diagnosable serious medical or mental disorder. We would define Criterion D by the abuse of substances (e.g. alcohol, caffeine, nicotine, or drugs), or by the use of prescription medication. Lastly, we would define E as a currently diagnosable sleep disorder, i.e. narcolepsy/cataplexy, periodic limb movements or restless legs, parasomnias, circadian rhythm sleep disorders, and insomnia disorder, and in conjunction with PSG screening (e.g. for sleep apnea and periodic limb movements). Moreover, the presence of a significant health disorder, without associated sleep disruption, may be unlikely given the overlap of sleep with general health1, 41. While the final three components (C, D and E) seem particularly applicable within a medical setting, they may not be appropriate or necessary for use in all research settings, to ensure normal sleepers are selected.

Defining normal sleep: A research agenda

All of these components can be assessed in different ways, such as by simple self-reports (e.g. do you have insomnia?), a personal history (e.g. a previous diagnosis), evidence of symptoms (e.g. screening measures or PSG), and a diagnostic clinical interview by trained experts. The precise levels of assessment applied would depend on, for example, the number of subjects to be tested, access to resources (e.g. PSG, laboratory facilities), and the experience of the researcher (e.g. in diagnosing the presence of a disorder). To aid standardization across the field, we suggest that precise definitions, exclusion criteria, and descriptive information, are reported as much as possible. Furthermore, the use of standardized methods, such as the consensus sleep diary[23], will help to aid comparisons between studies, as the precise contents of sleep diaries can vary between laboratories. In

addition, Edinger et al.[2] recommend reporting information as to the methods of recruitment and types of individuals, and the criteria for normal sleep may need to be tailored, for example, in elderly subjects[34]. Here we suggest specific assessment tools thought sufficient to identify normal sleepers, favouring questionnaire methods and aiming to reduce the burden on participants as much as possible (see Figure 2).

Means, standard deviations, and ranges are also recommended to be reported for common sleep measures, as well as quantitative thresholds, and the measures from which these are derived. Indeed, we found sleep diaries to be often used, although full descriptive information, as stated above, was not always reported. Edinger et al.[2] report that most insomnia studies describe control subjects as being without sleep complaints or insomnia. Exclusions were found to made for medical disorders which commonly affect sleep (~50%), symptoms of psychiatric disorder (~42%), psychoactive agents (~23%), evidence of sleep timing disruption (~15%), normal sleep values (~8.5%), or primary sleep disorders (<4%), and over 85% of samples were selected based on less than three of these criteria; results which also appear broadly consistent with the present review. However, in our sample of primary or physiological insomnia patients and controls, these values are higher overall, and in both studies sleep timing measures are among the least reported. Here we suggest a definition of normal sleep, for use with control subjects in contrast to patients, and in studies of healthy sleepers (e.g. sleep deprivation paradigms). Furthermore, this may be of particular importance in student populations, whose sleep has been described as “erratic”[27].

[Please insert Figure 2]

With regards to specific criteria as to normal sleep parameters, studies of insomnia have previously defined criteria for normal sleepers[29, 42]. For example, papers may define sleep parameter thresholds for insomnia subjects, such as a sleep-onset latency or wake-time after sleep onset duration of greater than 30 minutes, total sleep time less than six hours, and sleep efficiency less than 85%[42, 43], and it could be possible to extrapolate criteria for normal sleepers from such reports. Furthermore, studies of sleep deprivation and epidemiological studies provide evidence of the effects of sleep manipulations, and of normal ranges within the general population. In the absence of existing specifications for normal sleep, we would suggest the following definition and possible measurement tools.

Firstly, an individual does not meet criteria for an existing sleep disorder (i.e. insomnia disorder, circadian rhythm sleep disorder, sleep apnea, narcolepsy/cataplexy, periodic limb movements or restless legs syndrome, or a parasomnia). We suggest that the presence of periodic limb movements or restless legs syndrome, and sleep apnea should be assessed via polysomnography. Espie[44] has developed a screening algorithm for CRSD, parasomnias, restless legs syndrome or periodic limb movements, sleep apnea, and narcolepsy (Supplemental Material 2). The ISI[6] can be used to assess the severity of insomnia symptoms in those with a sleep complaint, and sleep complaints together with daytime sleepiness may be indicative of a circadian rhythm sleep disorder (CRSD)[45]. The sleep disorders questionnaire can also be used to assess sleep apnea, narcolepsy, and restless legs syndrome or periodic limb movements[46]. The diagnosis of narcolepsy without cataplexy has been described in greater depth in 2014[47]. In order to reduce the questionnaire burden on research participants, we suggest that the brief screening algorithm developed by Espie[44] should be used to identify the likely presence of narcolepsy, parasomnias, and circadian rhythm sleep disorders, and used to confirm a lack of sleep apnea, periodic limb movements or restless legs syndrome. However, the questions here are minimal, and PSG would

provide a higher level of evidence. Furthermore, actigraphy can be used to assess CRSD, and the Sleep Condition Indicator[48] can be used to screen for insomnia disorder.

Secondly, an individual should report no adverse daytime effects associated with poor sleep, at least within the previous week. Questionnaire measures could also be used to assess this, such as question 7 of the ISI[6], or component 7 of the PSQI[5]. Thirdly, an individual should report general satisfaction with their sleep, which can be assessed via the subjective components of a sleep diary[23], component 1 of the PSQI[5], or question 4 of the ISI[6]. We suggest that question 6 of the PSQI – 'During the past month, how would you rate your sleep quality overall?' should be used to assess general sleep satisfaction. For no adverse daytime effects of poor sleep, PSQI questions 7, 8 and 9 could be used, with complaints less frequently than once or twice a week. Alternatively, ISI question 3 could be used to assess this, as could questions 5, 6, and 7 of the Sleep Condition Indicator[48]. Fourthly, we suggest specific definitions of sleep parameters which we would suggest are indicative of normal sleep. In particular, we suggest thresholds for sleep duration, sleep continuity, time in bed, and sleep timing.

Typical sleep duration criteria are included, in keeping with a recent description of sleep health[49], and as short sleep duration/sleep restriction is linked to negative effects on health[1, 41, 50] and mortality[51]. Individuals with insomnia, who also have a short sleep duration, also seem to experience a more severe disorder (depression, heart and metabolic health)[52]. As an excessive sleep need, or time in bed, can be indicative of mood disorders[53], we would define normal sleep by a sleep duration of less than nine hours a night, and more than five hours a night (in the absence of diminished sleep continuity). Furthermore the amount of sleep typically achieved should be consistent with sleep need (c.f.[1, 49]), and this is affected by factors such as age[27, 34].

Sleep restriction also affects the ability to judge sleep need well[54]. For example, a study with "naturally short sleepers" found that many potential subjects reported that their short sleep duration was associated with work or care-giving, or poor physical or mental health. Indicators of naturally short sleep duration included that these sleepers did not seem to be making up for lost sleep at weekends, and had identical Epworth Sleepiness Scale (ESS) scores as control subjects. These subjects slept on average for 6 hours a night or less, and were found to show significantly greater evidence of hypomanic symptoms[55]. These studies taken together indicate that there are few people who are naturally short sleepers, and those who are evidence signs of mood disruption. However, these guidelines will require testing and ultimately there will be a trade-off between sensitivity and specificity. We would suggest that sleep timing be assessed via questions one and three of the PSQI, or via the Sleep Timing Questionnaire[38] (STQ). Sleep duration could be assessed via the PSQI, with question 8 (daytime sleepiness) used to assess whether sleep need is being met. These measures combined implicitly set limits on time in bed.

On measures of sleep continuity, sleep onset latency, wake time after sleep onset, and early morning awakenings should each be less than 30 minutes, with a sleep efficiency of greater than 85%. These components can be assessed via sleep diary[23] or the PSQI[5]. With regards to sleep scheduling, ordinarily, the timing of sleep should be consistent with a 9am-5pm work pattern. We would suggest a typical bed-time of between 22:00-01:00, with a rise time of 06:00-09:00. Furthermore, these times should not vary markedly, with sleep times consistent, within an hour, most days a week. The Sleep Timing Questionnaire[38], and sleep diaries[23], can be used to assess sleep timing and stability. However, ideally, all components of normal sleep could be captured by the use of a single measure, and sleep diaries are not always practical. While a comprehensive definition of good sleep in contrast to normal sleep

is beyond the scope of the present review, we suggest documenting applied criteria, to allow for future work in this area (see Figure 3). Furthermore, these components are consistent with those recently identified by Buysse[49] (sleep duration, efficiency/continuity, timing, alertness, and satisfaction), as being important for sleep health. A sleep health questionnaire was also described[49].

Additional criteria might be needed for the screening/selection of good sleepers, such as the endorsement of good sleep, alongside the absence of complaint. Good sleepers and normal sleepers could be somewhat different subject groups, and this could be worth investigating further. For example, three hypotheses may be made as to their differences. Firstly, good sleepers may be less likely to report or experience sleep disruption. Secondly, the effects of sleep loss on daytime functioning could be less severe, or minimal, for good sleepers. Thirdly, good sleepers could have a general resilience against poor health and towards well-being. For example, the Ford Insomnia Response to Stress Test (FIRST) can be used to assess vulnerability towards sleep disruption[56], and the importance of sleep adaptability has been recognized theoretically[25, 49]. Understanding this resilience to poor sleep/insomnia could have important implications for individuals and organizations, where sleep disruption may be expected.

As a result of this review, we have developed the Revised Research Criteria for Defining Normal Sleeper Controls (Figure 3.) for use with control subjects. Here, we suggest four main components of normal sleep, i.e. sleep disruption, circadian disruption, sleep disorders, and general health, which includes each of the 5 components previously identified[2]. We would define sleep quality with three subcomponents, which are: sleep duration and continuity, subjective sleep impression, and its impact on functioning. Sleep timing includes habitual bed and rise times, and their impact, as well as sleep timing stability. With regards

to other sleep disorders, four key sleep disorders are most relevant to screen for, i.e. narcolepsy/cataplexy, sleep disordered breathing or sleep apnea, parasomnias, and restless legs and periodic limb movements. Insomnia disorder and circadian rhythm sleep disorders can be assumed to be covered within sleep quality and sleep timing (see Image 3). Under general health, we have combined C and D of the RDC, and included mental and physical health with medication use and substance abuse. However, extreme levels of substance abuse would overlap with mental health (i.e. at the level of a substance abuse disorder), and substance abuse would include illicit drugs as well as, for example, nicotine, alcohol, and caffeine.

[Please insert Figure 3]

In summary, while results suggest that in general the methods of assessing normal sleepers cover the key components of normal sleep as specified by Edinger et al.[2], there is variability in the exact procedures used by different laboratories. However, an important limitation of the present results is that review papers used a well-defined insomnia sample, and results may differ if a broader inclusion criterion was used. It should also be noted that some of the studies reviewed may have begun before the publication of the RDC in 2004, and were published afterwards. Nonetheless, even within the current sample important issues in identifying controls were identified. Different fields could also apply different definitions to normal sleepers/control subjects, and we agree with Edinger et al.[2] that “due to this lack of standardization, synthesizing results of multiple … studies is a difficult if not impossible task”. As a first step, greater reporting of descriptive sleep information would aid in clarifying the exact nature of control groups. If screening of sleep disruption and timing can be clarified, additional methods could be redundant, and this would help reduce the burden on controls. While existing measures, such as the Pittsburgh Sleep Quality Index[5] and Insomnia Severity

Index[6], provide ranges for a lack of sleep disruption, these measures are not used consistently. Furthermore, as predominately global measures, these questionnaires do not tend to be reported at the item-level, and do not address all components of the RDC[2]. The use of this criteria for normal sleep would help clarify how the components of the RDC are assessed, aiding the understanding of how insomnia develops, as well as the nature of good sleep itself, by helping to standardize this field.

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Figure 1. Literature search strategy

Figure 2. Definition of normal sleep and assessment tools

Figure 3. Revised Research Diagnostic Criteria for Defining Normal Sleeper Controls

Table I. Summary of papers meeting inclusion criteria

	1st Author	Year	Control N	Age	Gender	Insomnia patients
1	Bastien	2013	30	35.8 (9.1)	18F, 12M	Psychophysiological insomnia, paradoxical insomnia
2	Huang	2012	48	38 (12)	28F, 20M	Primary insomnia
3	Israel	2012	22	26.5 (7.3)	19F, 3M	Primary insomnia
4	Morgan	2012	17	36 (9)	9F, 8M	Primary insomnia
5	Corsi-Cabrera	2012	10	25.6 (4.6)	5F, 5M	Primary insomnia
6	Forget	2011	12	44.3 (9.4)	7F, 7M	Primary insomnia
7	De Zambotti	2011	8	23.23 (3.24)	5F, 3M	Primary insomnia
8	Nissen	2011	53	46.9 (4.65)	32F, 21M	Primary insomnia
9	Spiegelhalder	2011	46	37.3 (11.4)	27F, 19M	Primary insomnia
10	Manconi	2010	288	58.5 (7.23)	176F, 112M	Primary insomnia
11	Winkelman	2010	15	38.8 (5.3)	6F, 9M	Primary insomnia
12	Deuschle	2010	827	54.6 (17.2)	455F, 372M	Primary insomnia
13	Spiegelhalder	2010	30	48.3 (12.9)	21F, 9M	Primary insomnia
14	Parrino	2009	20	45 (8)	16F, 4M	Paradoxical insomia
15	Lanfranchi	2009	13	42 (9)	9F, 4M	Primary insomnia
16	Buysse	2008	25	30.6 (7.4)	15F, 10M	Primary insomnia
17	Winkelman	2008	16	37.6 (4.5)	7F, 9M	Primary insomnia
18	Feige	2008	100	41.12 (13.99)	54F, 36M	Primary insomnia
19	Spiegelhalder	2008	20	38.6 (10.1)	12F, 8M	Primary insomnia
20	Bastien	2008	16	36.81 (10.19)	10F, 6M	Psychophysiological insomnia
21	Edinger	2008	84	48.6 (16.8)	41F, 43M	Primary insomnia
22	Sagaspe	2007	13	45 (12)	5F, 8M	Psychophysiological insomnia
23	Orff	2007	17	36.1 (7.1)	13F, 4M	Primary insomnia
24	Riemann	2007	8	46.3 (14.3)	5F, 3M	Primary insomnia
25	Robertson	2007	15	27.7 (7.05)	8F, 7M	Psychophysiological insomnia
26	Yang	2007	15	34.3 (12.9)	10F, 5M	Primary insomnia
27	Buysse	2007	18	27.2 (7.9)	15F, 3M	Primary insomnia
28	MacMahon	2006	20	28.2 (10.1)	11F, 9M	Primary insomnia
29	Ouellet	2006	14	30.00 (10.05)	5F, 9M	Insomnia syndrome (DSM-IV and ICSD)
30	Nissen	2006	7	44.9 (4.1)	4F, 3M	Primary insomnia
31	Marchetti	2006	30	23.2 (1.69)	15F, 15M	Psychophysiological insomnia
32	Carney	2006	104	47.3 (16.8)	52F, 52M	Primary insomnia
33	Lineberger	2006	88	45.39 (16.59)	44F, 44M	Primary insomnia
34	Rioux	2006	11	48.00 (7.86)	5F, 6M	Primary insomnia
35	Salin-Pascual	2006	6	26.6 (5.0)	4F, 2M	Primary insomnia
36	Thacher	2006	10	34.7 (7.9)	7F, 3M	Primary insomnia
37	Devoto	2005	7	22.6 (2)	4F, 3M	Primary insomnia

Table 2. Summary of adherence to RDC Criteria. '+' indicates full adherence to criteria, and '-' indicates apparent non-adherence.

	1st Author	Year	Criterion A	Criterion B	Criterion C	Criterion D	Criterion E
1	Bastien	2013	-	-	+	+	+
2	Huang	2012	-	-	+	-	+
3	Israel	2012	-	-	+	+	+
4	Morgan	2012	-	-	+	+	-
5	Corsi-Cabrera	2012	-	+	-	-	+
6	Forget	2011	-	-	+	-	+
7	De Zambotti	2011	-	+	+	+	-
8	Nissen	2011	-	-	+	-	-
9	Spiegelhalder	2011	-	+	+	-	+
10	Manconi	2010	-	-	-	-	-
11	Winkelman	2010	-	+	+	+	-
12	Deuschle	2010	-	-	-	-	-
13	Spiegelhalder	2010	-	-	-	-	-
14	Parrino	2009	-	-	-	-	+
15	Lanfranchi	2009	-	+	+	+	+
16	Buysse	2008	-	-	+	+	+
17	Winkelman	2008	-	+	+	+	+
18	Feige	2008	-	+	+	+	+
19	Spiegelhalder	2008	-	-	-	-	-
20	Bastien	2008	+	-	+	+	+
21	Edinger	2008	-	-	+	-	+
22	Sagaspe	2007	-	+	-	-	+
23	Orff	2007	-	+	+	+	+
24	Riemann	2007	-	-	+	-	-
25	Robertson	2007	-	-	+	+	-
26	Yang	2007	-	+	+	+	+
27	Buysse	2007	-	-	+	+	+
28	MacMahon	2006	-	-	-	-	-
29	Ouellet	2006	-	+	+	-	-
30	Nissen	2006	-	-	+	-	-
31	Marchetti	2006	+	-	-	-	-
32	Carney	2006	-	-	+	-	+
33	Lineberger	2006	-	-	+	+	+
34	Rioux	2006	+	-	+	-	-
35	Salin-Pascual	2006	-	-	-	-	-
36	Thacher	2006	-	-	+	+	+
37	Devoto	2005	-	-	-	-	-

Supplemental Material I. Summary of methods applicable to RDC Criteria. '+' indicates full adherence to criteria, and '-' indicates apparent non-adherence.

	1st Author	Year	Criterion A	Criterion B	Criterion C	Criterion D	Criterion E
1	Bastien	2013	Self-defined good sleepers. Reported being satisfied with their sleep, and had no subjective complaints of sleep difficulties, and did not meet diagnostic criteria for insomnia, via the Insomnia Diagnostic Interview. Sleep diary sleep efficiency scores were > 85%. Sleep efficiency, total wake time, total sleep time, and time in bed means and standard deviations (from sleep diary) also reported. ISI scores were < 8, means and standard deviations reported. Means and standard deviations for PSG and associated sleep diary measures also reported.	PSG bedtime was determined according to sleep diary reported bedtime.	Exclusion criteria for all participants were: presence of a significant current medical or neurological disorder that compromises sleep. Exclusion criteria for all participants were: presence of a major psychopathology, via the Structured Clinical Interview for DSM-IV Axis 1 disorders, or Beck Depression Inventory score > 15. Questionnaires: Beck Depression Inventory and the Beck Anxiety Inventory. Means and standard deviations for both reported.	Exclusion criteria for all participants were: alcohol or drug abuse in the past year. Exclusion criteria for all participants were: use of sleep-promoting agents. Exclusion criteria for all participants were: use of psychotropic or other agents known to affect sleep. Before testing: refrain from alcohol, nicotine, excessive caffeine, drugs.	Exclusion criteria for all participants were: evidence of another sleep disorder, such as sleep apnea or periodic limb movements during sleep. PSG: Apnea-Hypopnea Index > 15; Myoclonic Index With Arousal > 15.
			-	-	+	+	+
2	Huang	2012	Subjects met selection criteria for good sleeper controls.	PSG sleep was scheduled to match their habitual sleep	During the pre-screen, a routine medical examination was	During the pre-screen, a checklist of past medical history,	Subjects who had symptoms suggesting another sleep

				schedule. Means and standard deviations for PSG and associated sleep diary measures were reported.	conducted, a history of present illness was collected and a checklist of past medical history and personal history. Subjects who had major medical conditions or had a body mass index > 30 were not enrolled. Exclusion criteria for mental disorders were used according to the DSM-IV.	medications, and personal history (e.g. family situation, cigarettes, alcohol and illicit drug use) was completed. Exclusion criteria for substance abuse (alcohol, caffeine, or drug use) were used according to the DSM-IV.	disorder (e.g. heavy snoring, restless leg syndrome) were not enrolled. PSG: subjects were also excluded for an apnea-hypopnoea index > 5, or a periodic limb movement index > 5.
				-	-	+	-	+
3	Israel	2012	Good sleeper control group consisted of individuals who did not meet diagnostic criteria for insomnia. PSG sleep means and standard deviations reported.	PSG: Participants slept at their habitual sleep times as determined by sleep diary. Habitual sleep times (bed times/GNT and awakening times/GMT) were reported with means and standard deviations.	Exclusion criteria included significant or unstable medical conditions (e.g. unstable hypertension, hyper- or hypo-thyroidism, seizure disorders, neurodegenerative disease). Body mass index was recorded (means and standard deviations reported). Exclusion criteria included current psychiatric disorders (e.g. major depression). Questionnaires: the Inventory of Depressive Symptomology was used to quantify self-reported symptoms of depression (means and standard deviations reported).	Exclusion criteria included use of medications known to affect sleep or wake function. Exclusion criteria included current psychiatric disorders (e.g. drug dependence), and excessive caffeine and alcohol use.	Exclusion criteria included other current sleep disorders. PSG: Apnea-hypopnea index or leg movement arousal index $\geq$ 15.
				-	-	+	+	+

4	Morgan	2012	Were included for Insomnia Severity Index scores < 4. Means and standard deviations reported for ISI and PSQI. Means and standard error of mean reported for PSG measures.	All participants reported a typical bedtime of between 20:00 and 01:00. For one week prior to PSG, participants were instructed to maintain a regular schedule for time in bed (within one hour of their regular time), and to try to ensure at least 8 hours of in bed. At testing, slept at home at their regular bedtimes. Sleep diary based means and standard deviations of bedtimes and waketimes reported.	No subject had a history of major medical or neurological illness and none exhibited signs or symptoms of current medical or neurological illness as determined by physical examination and screening laboratory testing. Subjects were excluded for a previous diagnosis or historical evidence for unresolved chronic pain or gastroesophagael reflux disease. BMI means and standard deviations reported. Subjects were excluded if they had a personal history of psychiatric disorders, or if a first-degree relative was suspected of having depression.	Use of neuroactive prescription medication (including but not limited to sedative/hypnotics, antidepressants, anxiolytics, antipsychotics, opiate pain medication, muscle relaxants, and stimulants) in the past 3 months was exclusionary. Subjects were excluded if they reported a lifetime history of substance dependence, reported substance abuse in the past 6 months, had a positive urine test for drugs at screening (THC, opiates, cocaine, amphetamine, methamphetamine, benzodiazepines, barbiturates, and PCP), or drank more than the caffeine equivalent of 3 cups of coffee per day (or used caffeine after 19:00 more than once every two weeks). Numbers of smokers reported. Daily caffeine use means and standard deviations reported. Before testing: all subjects agreed to refrain from all psychoactive	Excluded for a previous diagnosis or historical evidence for sleep disordered breathing, restless leg syndrome, periodic limb movement disorder, sleep paralysis, nocturia, enuresis, narcolepsy, REM behavior disorder.

						substances (including alcohol) for 2 weeks before MRS. Exceptions to this were the continued caffeine use equivalent of ≤ 3 cups of coffee (as long as no caffeine was consumed after 19:00, and daily nicotine use could be continued.	
			-	-	+	+	-
5	Corsi-Cabrera	2012	No complaints of insomnia, reported sleep as restorative and satisfactory. Absence of sleep complaints verified by sleep diary. The Pittsburgh Sleep Quality Index and the Athens Insomnia scale were also used to further confirm sleep complaints, and means and standard deviations were reported. Hyperarousal scale, insomnia severity index, and subjective sleep diary means and standard deviations reported. PSG sleep means and standard deviations reported.	Regular sleep habits. Sleep logs verified regular bedtime hours 22:00 – 24:00 to 06:00 – 08:00. Potential participants with phase-delay insomnia were excluded.	Clinical histories were recorded and a psychiatric interview was conducted. Questionnaires: below cut-off for moderate depression on both the Beck Depression Inventory and the Hamilton Depression Scale, means and standard deviations reported.	Absence of medications and drugs were corroborated before PSG with the Multi Drug 6 Panel Urine Test.	Subjects had not suffered other sleep disorders. Absence of respiratory sleep disorders and periodic limb movements was further corroborated by PSG.
			-	+	-	-	+
6	Forget	2011	Controls had no sleep related difficulties or	Excluded if usual bedtime was before 21:00 or	Exclusion criteria were the presence of any	Not taking any medication that could interfere	Exclusion criteria included the presence of sleep

			daytime consequences and were satisfied with their sleep. Reported average sleep durations > 7 hours per night and sleep efficiencies > 85%. Questionnaires: Insomnia Severity Index and sleep diary, with means and standard deviations reported. PSG means and standard deviations also reported.	after 24:00. At PSG, bedtime was fixed between 21:00 and 24:00, and wake time was fixed between 05:00 and 08:00, with usual schedules accommodated within 30 mins.	medical condition interfering with sleep (e.g. chronic pain). Also any hearing problem that could interfere with the task. Exclusion criteria included the presence of a depressive or anxiety disorder or any other psychiatric disorder as determined by the Structured Clinical Interview for DSM-IV. Currently receiving psychological treatment. Questionnaires: Beck Depression Inventory and Beck Anxiety Inventory, with means and standard deviations reported.	with sleep. At testing: alcohol or caffeine at least 8 hours before PSG.	problems, e.g. sleep apnea or periodic limb movements during sleep. PSG: apnea-hypopnea index > 15, myoclonic index with arousal > 15.
			-	-	+	-	+
7	De Zambotti	2011	Controls had to report Pittsburgh Sleep Quality Index scores of < 6, Insomnia Severity Index scores < 11, and Athens Insomnia Scale scores of < 6. Questionnaires: Hyperarousal Scale, Pittsburgh Sleep Quality Index, Insomnia Severity Index, Athens Insomnia Scale, Epworth Sleepiness Scale, Stanford Sleepiness Scale and Pre-Sleep Arousal	Exclusions included shift work or long range travel in the previous six months. Circadian disorders were excluded. PSG lights off at 24:00 and on at 08:00.	Exclusion criteria were medical conditions, or BMI $\geq$ 30, and psychiatric conditions. Questionnaires: Beck Depression Inventory, State Trait Anxiety Inventory means and standard deviations were reported.	Medicines affecting the cardiovascular system, or psychoactive drugs, were exclusion criteria. All subjects were drug-free. Subjects were asked to refrain from alcohol, caffeine, and tobacco on test day and day before.	Circadian disorders were excluded (via sleep diary and actigraphy).

			Scale means and standard deviations reported. PSG means and standard deviations also reported.				
			-	+	+	+	-
8	Nissen	2011	Good sleeper status was ensured by a clinical interview and sleep diary. PSQI and PSG means and standard deviations recorded.	Sleep diaries ensured that the subjects' usual sleep times approximated those of the laboratory, within an hour. PSG was recorded from 22:30 to 06:30.	Extensive examination to rule out any comorbid physical or psychiatric disorder, including a Composite International Diagnostic Interview.	Free of medication for at least 2 weeks before study onset. A urine drug screening after the sleep laboratory night confirmed that all participants were free of any benzodiazepines, barbiturates, amphetamines, or opiates. All subjects were non-smokers. Alcohol and caffeine were not consumed during the study.	Good sleeper status ensured by clinical interviews and sleep diaries.
			-	-	+	-	-
9	Spiegelhalder	2011	Healthy controls (clinical exam). Means and standard deviations of PSQI scores were reported. Means and standard deviations of PSG parameters were reported.	Ruled out circadian rhythm sleep disorders. PSG lights out at 23:00, lights on at 07:00.	All participants underwent a standard physical examination, including electrocardiogram, electroencephalogram, and routine laboratory investigations (blood cell count, liver, renal, and thyroid function) to exclude those with serious medical conditions. No subjects had a history of cardiovascular illness. Mean and standard deviations of BMI were reported.	Subjects were free of psychoactive, cardiac, or antihypertensive medication at least one week before testing. Permitted substances included adequate thyroid and iron substitution and oral contraceptives. Numbers of smokers were reported. Subjects were asked to refrain from alcohol and caffeine during two days of	Ruled out occult sleep disorder pathology (including hypersomnia, parasomnia, sleep-related breathing disorder, sleep-related movement disorder, and circadian rhythm sleep disorder). PSG: periodic leg movements during sleep arousal index > 5, or a sleep apnoea index of > 5 were excluded.

					A physician examined all participants to rule out any psychiatric disorders. Means and standard deviations of the BDI were reported.	testing.	
			-	+	+	-	+
10	Manconi	2010	The Sleep Heart Health Study cohort was used to identify normal controls via a computerized algorithm. Objective and subjective total sleep times depicted via graphs.	N/A	Selection criteria included the absence of cardiovascular or respiratory disease, asthma, chronic obstructive pulmonary disease, or diabetes mellitus.	Participants using any sedative or hypnotic medications were excluded.	Selection criteria included the absence of sleep-disordered breathing. PSG: apnoea-hypopnoea index > 5.
			-	-	-	-	-
11	Winkelman	2010	Good sleepers had no sleep complaints or history of sleep disorders. Actigraphy was used to verify sleep diary information. PSQI and sleep diary and actigraphy means and standard deviations reported.	Exclusion criteria included work history of swing shift, night shift, or rotating shift within the preceding year.	Exclusion criteria included symptoms of significant head trauma or loss of consciousness > 30 mins; BMI > 32 or < 19.8 (means and standard deviations reported). Pregnancy and reproductive hormone testing. Exclusion criteria included current or recent (within the preceding year) diagnosis of a DMS-IV Axis 1 disorder. Lifetime history of psychiatric disorder via the Structured Clinical Interview for DSM-IV. Questionnaires: Derogatis Stress profile (means	Exclusion criteria included regular treatment (> 1 time/week) with CNS-active agents within 3 months of the first visit. Exclusion criteria included DSM-IV alcohol or drug dependence/abuse. Current smoking of more than 10 cigarettes per day. Consumption of ≥ 2 caffeinated beverages per day or more than two standard alcoholic drinks per day for a period of > 1 month within the preceding year. Toxicology screen for illicit substances.	Exclusion criteria included any clinically significant signs, diagnosis, or history of any sleep disorder.

					and standard deviations reported).		
		-	+	+	+	-	
12	Deuschle	2010	Healthy control subjects.	N/A	Those with no personal history of current or past psychiatric disorders, via SCID-I for DSM-IV Axis 1 disorders (mood disorders, psychotic disorders, anxiety disorders, eating disorders, and somatoform disorders) were included.	Those with no substance use disorders (SCID-I).	N/A
		-	-	-	-	-	
13	Spiegelhalder	2010	Healthy good sleepers. Means and standard deviations of PSQI and SSS scores reported.	Tasks were carried out in the evening between 16:15 and 22:15.	Means and standard deviations of BMI reported.	N/A	N/A
		-	-	-	-	-	
14	Parrino	2009	Healthy subjects without sleep complaints, personal interview and sleep logs confirmed normal sleep habits without any difficulty falling asleep or remaining asleep at night. St. Mary's questionnaire was used to assess subject sleep quality and continuity. PSG and subjective sleep means and standard deviations reported.	Normal sleep habits.	Free of psychiatric, neurological or medical disorders.	Abstained from alcohol, caffeine and drugs for 2 weeks up to the study.	PSG: exclusions for apnea-hypopnea index and periodic limb movements < 5.
		-	-	-	-	+	
15	Lanfranchi	2009	Good sleepers were defined by	Exclusion criteria included unusual	Exclusion criteria included	Exclusion criteria included	Exclusion criteria included sleep

			a self-reported sleep latency and/or wake after sleep onset < 30 mins, with a total sleep time at least 7 hours, and sleep efficiency > 85%, for 6 days a week. ISI < 8 (means and standard deviations reported). Means and standard deviations of subjective and PSG sleep reported.	sleep schedule (bedtime after 24:00 and wake-time after 09:00), or shift work. PSG lights off at usual bedtime, lights on at 08:00.	hypertension and other cardiovascular diseases, neurological degenerative disorders (e.g. dementia, multiple sclerosis), diabetes. BMI > 32 (means and standard deviations reported). Exclusion criteria included current diagnosis of major depression, dysthymia, or anxiety disorders, Beck Depression Inventory scores ≥ 23 excluded (means and standard deviations reported).	medications affecting the central or autonomic nervous system, antihypertensive drugs. Exclusion criteria included smoking, alcohol abuse, drug abuse, or excessive caffeine use (> 3 cups/day).	disorders (including sleep apnea, restless legs syndrome, bruxism, and narcolepsy). PSG: apnea-hypopnea index ≥ 5, periodic leg movements ≥ 10 excluded.
			-	+	+	+	+
16	Buysse	2008	Exclusion criteria for good sleeper controls: current or past history of primary insomnia. Questionnaires: Hyperarousal Scale, Pittsburgh Sleep Quality Index, Multidimensional Fatigue Inventory, and Epworth Sleepiness Scale means and standard deviations reported. Means and standard deviations reported from sleep diary and PSG.	N/A	Medical history and physical examination, with routine blood work. Exclusion criteria included significant or unstable medical conditions. Psychiatric history using the Structured Clinical Interview for DMS-IV. Exclusion criteria included current major syndromal mood, anxiety, psychotic, or substance use disorder, and current or past history of any major psychiatric disorder. Questionnaires: Inventory of Depressive	Medication history and urine drug screen. Exclusion criteria included the use of medications or substances known to affect sleep, or substance use disorder. Exclusion criteria included coffee consumption equivalent of > 4 cups/24 hours, alcohol consumption > 14 drinks/week.	Sleep history using locally developed questionnaires and interviews to yield DSM-IV sleep disorder diagnoses. Exclusion criteria included a current sleep disorder. PSG: apnea-hypopnea index > 15, or periodic limb movement arousal index > 20.

					Symptomology, and Penn State Worry Questionnaire, and Beck Anxiety Inventory means and standard deviations reported.		
			-	-	+	+	+
17	Winkelman	2008	Normal sleepers without sleep complaints. Actigraphy data used to verify sleep-wake diary information. Questionnaires: Pittsburgh Sleep Quality Index. Means and standard deviations reported for the PSQI, and PSG sleep.	Exclusion criteria included work history of night shift, swing shift, or rotating shift within the preceding year. PSG lights out at the subjects' usual times.	Unstructured clinical interview for history of medical disorders. Laboratory assessment included electrolytes, CBC, liver and thyroid functions, pregnancy testing, and reproductive hormone testing. Exclusion criteria included a history of significant head trauma or loss of consciousness > 30 minutes, BMI > 32 or < 19.8 (means and standard deviations reported). Interview for lifetime history of psychiatric disorders with the Structured Clinical Interview for DSM-IV. Exclusion criteria included current or recent (within the preceding year) diagnosis of DSM-IV Axis 1 disorders.	Exclusion criteria included regular treatment (more than once per week) with CNS active agents, within 3 months of visit. Toxicology screen for illicit substances. Diagnosis of DSM-IV Axis I alcohol dependence or abuse. Exclusion criteria included current smoking of more than 10 cigarettes a day, consumption of more than 2 caffeinated beverages per day, or more than 2 standard alcoholic drinks per day, for any period over 1 month within past year.	Unstructured clinical interview for history of sleep disorders. Symptoms, diagnosis, or history of any sleep disorder. PSG: more than 15 apnea-hypopneas, or more than 20 periodic limb movements led to exclusion.
			-	+	+	+	+
18	Feige	2008	Healthy good sleeper controls, required PSQI < 6. Questionnaires: PSQI means and	Circadian rhythm disorders and history of shift work were exclusion criteria. PSG lights out at	History of medical illness, with urine drug screen (opiates, barbiturates, benzodiazepines, amphetamines,	Use of medication affecting sleep, drugs (positive urine drug screen) were exclusion criteria. Consumption of	Sleep disorders in first degree relatives (parents, siblings, and children). Exclusion criteria

			standard deviations reported. PSG and subjective sleep means and standard deviations reported.	23:00 and on at 07:00. PSQI habitual bedtimes were used to make sure that PSG times were not strongly different.	cannabis, and viral/bacterial infection) and routine blood tests (blood cell count, liver, renal and thyroid function). Excluded clinically relevant medical or neurological disorders and pregnancy, or any history of serious medical illness (e.g. hepatitis). Any history of psychiatric disorders was exclusionary. Questionnaires: Beck Depression Inventory.	hypnotic medication or medication known to affect sleep in the 2 weeks before study, or history of substance abuse were exclusion criteria. Refrained from alcohol and caffeine use restricted at testing.	were the presence of any sleep disorder (sleep apnea syndrome, restless-legs syndrome, narcolepsy, circadian rhythm disorders, organic or psychiatric insomnia). PSG: sleep apnea or periodic limb movements in sleep index with arousal $\geq$ 5.
			-	+	+	+	+
19	Spiegelhalder	2008	Healthy controls.	N/A	Healthy controls.	N/A	N/A
			-	-	-	-	-
20	Bastien	2008	Good sleepers reported being satisfied with their sleep, with no subjective complaints of sleep difficulties, or meeting criteria for insomnia disorder. Had to report ISI < 8 and sleep diary sleep efficiency > 84%. ISI, PSG and sleep diary means and standard deviations reported.	PSG time in bed was determined from habitual times reported in the sleep diary.	Exclusion criteria were the presence of a significant current medical (e.g. cancer, diabetes) or neurological disorder (e.g. dementia, Parkinson's disorder), which compromises sleep. Exclusion criteria included presence of a major psychopathology (e.g. major depressive disorder, anxiety disorder), via the Structured Clinical Interview for DSM-IV. Beck Depression Inventory score > 23 exclusionary.	Exclusion criteria included using sleep-promoting medication, psychotropic or other medications known to alter sleep (e.g. bronchodilators). Exclusion criteria included alcohol or drug abuse during the past year. Participants were asked to refrain from alcohol, drugs, and excessive caffeine or nicotine at testing.	Did not meet criteria for insomnia (Insomnia diagnostic interview). Exclusion criteria included evidence of another sleep disorder such as sleep apnea. PSG: apnea-hypopnea index >1 5, or periodic limb movements during sleep (myoclonic index with arousal) > 15.

					Beck Anxiety Inventory and Beck Depression Inventory means and standard deviations reported.		
			+	-	+	+	+
21	Edinger	2008	Non-complaining normal sleepers. Means and standard deviations from PSG and sleep diary reported.	N/A	No major medical condition that might have contributed to an unreported, occult sleep disorder. Study exclusion: sleep disruptive medical conditions, e.g. rheumatoid arthritis. Thyroid screening. No major psychiatric condition that might have contributed to an unreported, occult sleep disorder. Study exclusion: current major psychiatric (Axis 1) condition of the basis of a Structured Clinical Interview for Psychiatric Disorders (SCID).	Study exclusion: anxiolytics, antidepressants, or any other psychotropic medication, or sedative hypnotic dependence and unwillingness/inability to abstain from these medications while in the study.	Reported no sleep complaints or had a major condition that might have contributed to an unreported occult sleep disorder. Excluded normal sleepers who met criteria for any sleep disorder. PSG: apnea-hypopnea index $\geq$ 15, periodic limb movement-related arousal index $\geq$ 15.
			-	-	+	-	+
22	Sagaspe	2007	No sleep complaints. No insomnia complaints over 2 nights a week for the past 3 months. PSG sleep means and standard deviations reported.	Controls were excluded for abnormal usual sleep patterns, night shift or shift workers. PSG time in bed from 22:30-23:00 to 07:00.	Controls were in good health, as determined by a medical history and examination. Excluded those with organic disorders affecting sleep. All had normal vision and hearing. BMI means and standard deviations reported.	Free of medication.	Had no sleep complaints. Excluded if they had an Epworth Sleepiness Scale score > 9 (means and standard deviations reported), sleep complaints evoking an OSAS or insomnia complaints for more than two nights per week over the last 3 months, or poor sleep hygiene.

							PSG: apnea-hypopnea index and index of periodic limb movements in sleep, means and standard deviations reported.
			-	+	-	-	+
23	Orff	2007	GS must have reported < 15 mins to fall asleep, < 15 mins WASO, > 7 hour TST, > 89% sleep efficiency. There were no specific cut-off scores for daytime impairment. PSG sleep, PSQI, ESS, and MFI means and standard errors reported.	All subjects had a habitual bedtime of 20:00 – 24:00 and waketimes of 06:00-08:00, and were excluded if these fell outside this window minimize the potential for phase delay/advance. Bedtimes and risetimes according to habitual schedules. Testing sessions between 19:00 and 21:00.	Subjects were given a brief medical history and physical and had blood and urine chemistries done at intake. Excluded those with significant medical comorbidities and/or unstable or untreated medical conditions, a history of seizures or seizure disorder, who were pregnant or breastfeeding or had plans to become pregnant. Female participants were premenopausal or at least 2 years post menopausal. Evaluated for psychiatric illness with a PC-based Structured Clinical Interview from DSM-IV to rule out Axis 1 disorders. Participants also were excluded if they scored ≥ 10 on the Beck Depression Inventory or Beck Anxiety Inventory, or the Hamilton Depression Scale.	Subjects were excluded if they were currently taking medication known to affect sleep. Subjects were not enrolled if they smoked/used nicotine based products. During the study, subjects were allowed to consume moderate amounts of caffeine (1/2 cups per day, not after 12:00) and alcohol (1-2-serving/day not less than 4 hours before bedtime).	< 15 mins to fall asleep, < 15 mins WASO, > 7 hour TST, > 89% sleep efficiency. Subjects with sleep apnea or periodic limb movements detected on PSG were excluded. PSG: RDI > 5, PLMI > 5.
			-	+	+	+	+
24	Riemann	2007	Healthy good sleepers. PSQI means and	Habitual bedtimes and rising times reported.	No acute medical disorder. BMI (means and standard	Mediation free at least 2 weeks before study.	No acute sleep disorder.

			standard deviations reported.		deviations reported). Physical examination, daytime clinical EEG, routine ECG, blood tests (analyzed for blood cell count, thyroid, renal, and hepatitis function), and urine drug testing (for barbiturates, opiates, amphetamines, cannabis, and benzodiazepines). Acute and chronic medical and psychiatric disorders were thoroughly investigated and ruled out. Structured psychiatric diagnostic interview, Current or lifetime psychiatric disorders.	Urine drug testing.	
			-	-	+	-	-
25	Robertso n	2007	Normal sleepers, did not meet criteria for PI, reported satisfaction with their sleep and being typically good sleepers, including during the last month, and had to score PSQI < 5. Diary and actigraphy based means, medians and standard deviations reported, as were PSQI, ESS, and DBAS.	Followed normal routines during the study, testing times personalized.	Exclusion criteria were sleep disturbance attributable to a medical or psychiatric condition, significant depression symptoms > 23 on the Beck Depression Inventory; means, medians and standard deviations reported), receiving psychological treatment.	Excluded those on medication (sleep or otherwise), or for drug usage.	Local comprehensive sleep interview schedule. Symptomatic evidence of another sleep disorder (e.g. sleep apnea, restless leg syndrome, periodic limb movement disorder).
			-	-	+	+	-
26	Yang	2007	Normal sleepers, no history of	Inclusion criteria included not a	Inclusion criteria included no	Inclusion criteria included not	Subjects found to have other sleep

			current medical or psychiatric disorders that are associated with sleep disturbances. PSG sleep means and standard deviations reported.	shift-worker, with a regular sleep-wake schedule. Came in to laboratory 1 hour before habitual bedtimes. Range of habitual bed time and risetimes reported.	history of current medical or psychiatric disorders associated with sleep disturbances.	currently using medications that may affect sleep, at willing to stop at least 2 weeks prior to study. Inclusion criteria included: not a habitual coffee drinker (fewer than 2 cups of caffeinated drinks a day), or habitual alcohol user (fewer than 3 standard drinks per week); non-smoker or light smoker (fewer than 10 cigarettes a day). For at least three days before the study, refrain from alcohol, with max 1 cup of caffeinated beverages before (12:00).	disorders such as sleep-related breathing disorders or periodic limb movement disorders were excluded. PSG: Respiratory disturbance index > 5/hr, periodic limb movement index > 10/hr.
			-	+	+	+	+
27	Buysse	2007	Current or past history of PI. Multidimensional Fatigue Inventory, Hyperarousal Scale, PSQI, and ESS, and sleep diary means, standard deviations, and medians reported.	Testing scheduled to usual routines.	Evaluated with a medical history, physical examination, routine blood work and urine drug screen. Exclusion criteria included significant or unstable medical conditions. Psychiatric history was examined with the Structured Clinical Interview for DSM-VS. Exclusion criteria included current major syndromal mood, anxiety or psychotic disorder, current or past history of	Medication/substance history. Exclusion criteria included: substance abuse disorder; use of medicines or substances known to affect sleep; alcohol consumption of more than 14 drinks/week; coffee consumption equivalent of more than 4 cups a day. Urine drug screen. Range, means, and standard deviations of alcohol and caffeine use	Sleep histories using locally developed questionnaires and interviews to yield DSM-IV sleep disorder diagnoses. Current or past history of PI, current sleep disorder by clinical criteria. PSG: Apnea-hypopnea index > 15, periodic limb movement arousal index > 15.

				any major psychiatric disorder. Inventory of Depressive Symptomology, Penn State Worry Questionnaire, and Beck Anxiety Inventory means, standard deviations, and medians reported.	reported.	
			-	-	+	+	+
28	MacMahon	2006	Reported themselves as good sleepers, with no current or historical sleep disorder, and scored less than 5 on the PSQI.	MEQ-RF, BT and RT, means and standard deviations reported.	Normal vision. Interview for general psychological state (based on DSM-IV). Beck Depression Inventory (Fast Track), State and Trait Anxiety Inventory, National Adult Reading Test means and standard deviations reported.	Active drug interventions for sleep problems. Caffeine intake questionnaire. Exclusion criteria: substance misuse, drug interventions for sleep.	Met no criteria for current or past sleep disorder via an interview which covered the differential diagnosis of alternative sleep disorders (such as sleep apnea, based on ICSD). Exclusion criteria: active psychological or drug interventions for sleep problems.
			-	-	-	-	-
29	Ouellet	2006	Inclusion criteria: report no sleep complaints. Means and standard deviations reported for the ISI, MDFI, and Dysfunctional Beliefs About Sleep, sleep diary, and PSG sleep.	Inclusion criteria: report relatively regular sleep/wake schedules. Went to bed at their usual times (range reported).	Inclusion criteria: physically and mentally healthy. Means and standard deviations reported for the Beck Depression Inventory and the Beck Anxiety Inventory.	Inclusion criteria: not taking medication known to produce changes in sleep architecture.	Inclusion criteria: no sleep complaints. Participants completed PSG.
			-	+	+	-	-
30	Nissen	2006	Good sleeper status ensured by clinical interview and sleep diary. PSQI and PSG means and standard deviations reported.	Sleep diaries ensured usual sleep times approximated those in the laboratory. PSG from 22:30 – 06:30.	Extensive exam to rule out comorbid physical or psychiatric disorders. IQ means and standard deviations reported.	Free of medication at least 2 weeks before study, and refrained from alcohol and caffeine during study. All were non-smokers. Urine drug screen	Good sleepers.

						for benzodiazepines, amphetamines, opiates, and barbiturates at testing.	
			-	-	+	-	-
31	Marchetti	2006	Good sleepers were required to score < 5 on the PSQI, report themselves as good sleepers (who falls asleep as soon as your head touches the pillow and wakes up feeling refreshed in the morning), and met no criteria for current or historic sleep disorders. PSQI and sleep diary means and standard deviations reported.	L5 component of actigraphy means and standard deviations reported. Subjects were asked if they were a lark or an owl.	Scoring above the cut-off makers for depression resulted in exclusion. State Trait Anxiety Inventory and Beck Depression Inventory means and standard deviations reported.	N/A	Met no criteria for a sleep disorder at the present time or in the past.
			+	-	-	-	-
32	Carney	2006	Normal sleepers who reported no sleep complaints. Reported Dysfunctional Beliefs About Sleep scale means and standard errors.	N/A	Evidenced no major psychiatric or medical condition that might contribute to an occult sleep disorder. Excluded those with a medical condition which compromises sleep (e.g. rheumatoid arthritis, thyroid disease). Excluded those with a current major psychiatric disorder as evidenced by the Structured Clinical Interview for Psychiatric Disorders. Medical examination and	Excluded if showed sedative hypnotic dependence and were unwilling or unable to abstain from these medications during study. Taking anxiolytics, antidepressants, or any other psychotropic medication.	Structured sleep interview, excluded those who met criteria for any sleep disorder. PSG: apnea-hypopnea index $\geq$ 15, periodic limb movement related arousal index $\geq$ 15.

					thyroid screening.		
			-	-	+	-	+
33	Lineberger	2006	Non-complaining normal sleepers. Means and standard deviations of sleep diary measures reported.	N/A	Medical history, brief medical examination, and thyroid screening to rule out any additional sleep-disruptive medical conditions. Excluded those with a terminal illness, a medical condition (e.g. rheumatoid arthritis, thyroid disease) that compromises sleep), and those with abnormal thyroid-stimulating hormone levels on a screening hormone panel. Structured Clinical Interview for psychiatric disorder was used to rule out obvious or occult psychiatric disorders. Excluded those with a history of psychiatric illness, or who met criteria for a current major psychiatric (Axis I) condition.	Excluded substance abusers, those showing sedative or hypnotic dependence and were unable or unwilling to abstain from these medications during the study, and those taking anxiolytics, antidepressants, any other psychotropic medication.	Ruled out those with obvious or occult sleep disorders (e.g. obstructive sleep apnea, periodic limb movements), or met criteria for any sleep disorder. PSG: excluded those with an apnea-hypopnea index $\geq$ 15, periodic limb movement related arousal index $\geq$ 15.
			-	-	+	+	+
34	Rioux	2006	Good sleepers had to not meet inclusion criteria for insomnia, i.e. 1) Presence of a subjective complaint of insomnia, defined as difficulty initiating (i.e. sleep onset latency > 30 mins) and/or maintaining sleep (i.e. time awake after	Testing between 19:30 and 21:30.	Exclusion criteria were significant current medical (e.g. cancer, diabetes) or neurological disorder (e.g. dementia, Parkinson's disease) that compromises sleep. Beck Depression Inventory and Beck Anxiety Inventory means	Exclusion criteria included use of psychotropic or other agents known to alter sleep (e.g. bronchodilators); use of sleep-promoting agent (e.g. benzodiazepines) . Subjects were free from psychotropic drugs for at least a 2 week period	Exclusion criteria included presence of any sleep disorder (e.g. periodic limb movements, sleep apnea).

			sleep onset > 30 mins) present at least 3 nights a week; 2) insomnia duration of at least 6 months; 3) insomnia or its perceived consequences causing marked distress or significant impairment of occupational or social functioning (e.g. problem of concentration); and 4) presence of a subjective complaint of at least 1 negative daytime consequence attributed to insomnia (e.g. fatigue, mood disturbances). Good sleepers had to report being satisfied with their sleep. ISI and sleep diary means and standard deviations reported.		and standard deviations reported. Exclusion criteria included presence of a major psychopathology (e.g. major depressive disorder; anxiety disorders); or a score of 23 or higher on the Beck Depression Inventory. Subjects reported normal hearing.	prior to entry to the study.	
			+	-	+	-	-
35	Salin-Pascual	2006	Normal volunteers. Multiple sleep latency test means and standard deviations reported. Means and standard deviations of PSG sleep reported.	N/A	Normal volunteers	Subjects studied were not regular consumers of caffeine, cola beverage, or medication containing caffeine. No history of regular coffee consumption (> 5 cups of coffee/week on a regular basis). All were non-smokers who had never smoked.	PSG: apnea-hypopnea index > 5, periodic limb movements > 5.

			-	-	-	-	-
36	Thacher	2006	Good sleepers characterized their sleep as restorative and relatively imperturbable. Required subjects to have slept well (PSG sleep efficiency > 85%). Means and standard deviations reported for PSQI and PSG sleep.	Participants had stable sleep/wake schedules (no shift work), with preferred sleep phase between 22:00 and 08:00, corroborated with sleep diary. PSG bedtimes based on usual times.	Reported good physical and mental health, corroborated with the data collected at the intake interview, including questionnaires such as the Schedule for Affective Disorders and Schizophrenia – Lifetime Version, and a PC-based Structured Clinical Interview for DSM-IV-TR, a self-reported medical history inventory, and a self-report symptom checklist. Exclusion criteria included: current significant or unstable medical or psychiatric illness, or history within the past 5 years, and history of head injury, and not pregnant, intend to become pregnant, or relying solely on steroidal contraceptives as their means of birth control. Means and standard deviations reported for BMI, Beck Depression Inventory, and Hamilton Depression Inventory.	Exclusion criteria included any prescription medications that could interfere with PSG or sleep log, SSRIs within 6 months of study, investigational drug within 30 days, use prescription sleep medications within 14 days, or over-the-counter sleep medications within 14 days of study intake. Exclusion criteria included recreational drug use within 4 weeks of study.	Exclusion criteria included sleep disorders. PSG: Periodic leg movement index or respiratory distress index of > 5/ hour.
			-	-	+	+	+
37	Devoto	2005	Subjects with no sleep complaints were asked to participate.	P300 based on individual sleep schedules.	None of the participants reported a history of medical or psychiatric	Caffeine, alcohol, and drugs not used on study nights or the morning after.	Subjects with no sleep complaints were asked to participants (Sleep Disorders

	PSQI, actigraphy and sleep diary means and standard deviations reported.		disorders.	None of the participants reported a history of drug use.	Questionnaire).
	-	-	-	-	-